

Clinical Laboratory COVID-19 Response Call

Monday, April 20, 2020 at 3:00 PM EDT

- **Welcome and Introductions**
 - Jasmine Chaitram, CDC Division of Laboratory Systems
- **Laboratory Biosafety Update: Autopsy and Anatomic Pathology Guidance for COVID-19**
 - Bill Arndt, CDC Division of Laboratory Systems
- **COVID-19 Emergency Preparedness and Recovery Planning in Anatomic Pathology**
 - Vinita Parkash, Yale University School of Medicine
- **COVID-19 at Alameda Health System**
 - Valerie Ng, Alameda Health System
- **COVID-19 Coding and Reimbursement**
 - Sarah Shirey-Losso, Centers for Medicare and Medicaid Services (CMS)
- **Updates on Review Process, Quality, Validation, and Serology Testing**
 - Tim Stenzel and Sara Brenner, U.S. Food and Drug Administration (FDA)

Lab Week 2020



Division of Laboratory Systems (DLS)

[DLS Home](#)



Medical Laboratory Professionals Week



Medical Laboratory Professionals Week takes place the last full week each April and celebrates its 44th anniversary this year. The week is coordinated by a collaborative with representatives from 17 national clinical laboratory organizations, including CDC, to celebrate clinical laboratory professionals. [Learn More...](#)

CDC Information for Laboratories

UPDATED – Interim Guidance for Collecting, Handling, and Testing Clinical Specimens

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

UPDATED – COVID-19 Testing and Reporting by Laboratories: Q&A

<https://www.cdc.gov/coronavirus/2019-ncov/lab/testing-laboratories.html>

Diagnostic Tools and Virus

<https://www.cdc.gov/coronavirus/2019-ncov/lab/tool-virus-requests.html>

Emergency Preparedness for Laboratory Personnel

<https://emergency.cdc.gov/labissues/index.asp>

CDC Laboratory Outreach Communication System (LOCS)

<https://www.cdc.gov/csels/dls/locs/>

To Ask a Question

- Using the Webinar System
 - Click the **Q&A** button in the Zoom webinar system
 - Type your question in the **Q&A** box
 - Submit your question
 - Please do not submit a question using the chat button
- For media questions, please contact CDC Media Relations at media@cdc.gov.

Laboratory Biosafety Update for COVID-19

Bill Arndt, PhD
CDC Division of Laboratory Systems



Biosafety Resources

COVID-19 Information for Laboratories page:

<https://www.cdc.gov/coronavirus/2019-ncov/lab/index.html>

Interim Laboratory Biosafety Guidelines:

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html>

Laboratory Biosafety Frequently Asked Questions:

<https://www.cdc.gov/coronavirus/2019-ncov/lab/biosafety-faqs.html>

Send Inquiries to: DLSInquiries@cdc.gov

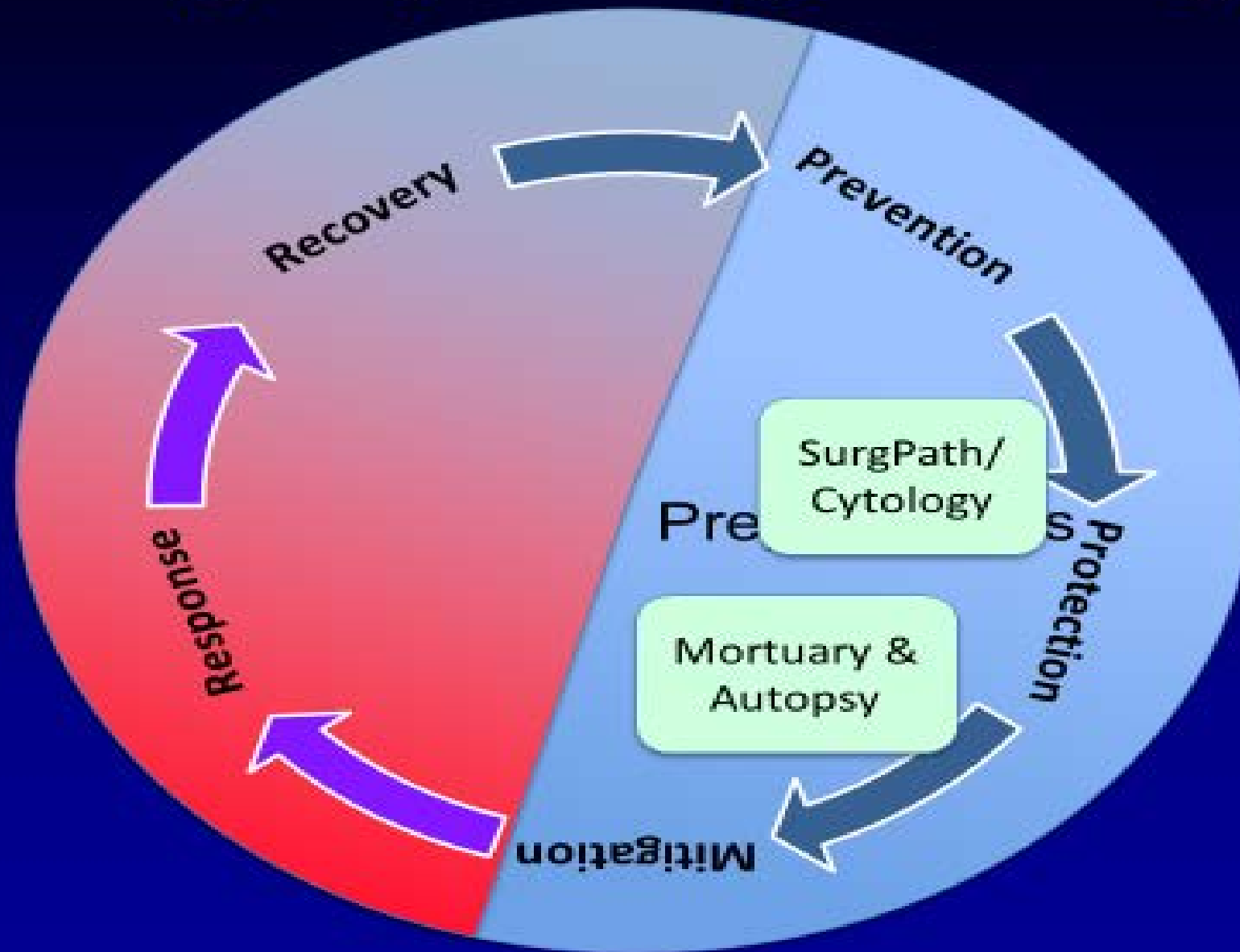
COVID-19 Emergency Preparedness and Recovery Planning in Anatomic Pathology

Vinita Parkash, Yale University School of Medicine



- 2001: Anthrax and 9/11
- Public Health Emergency Preparedness and Response Capabilities
 - Federal, State, Local
 - Hospitals > Mass Casualty Incident plans (TJC - EM 02.02.01)
- COVID 19 is a “never before” seen event

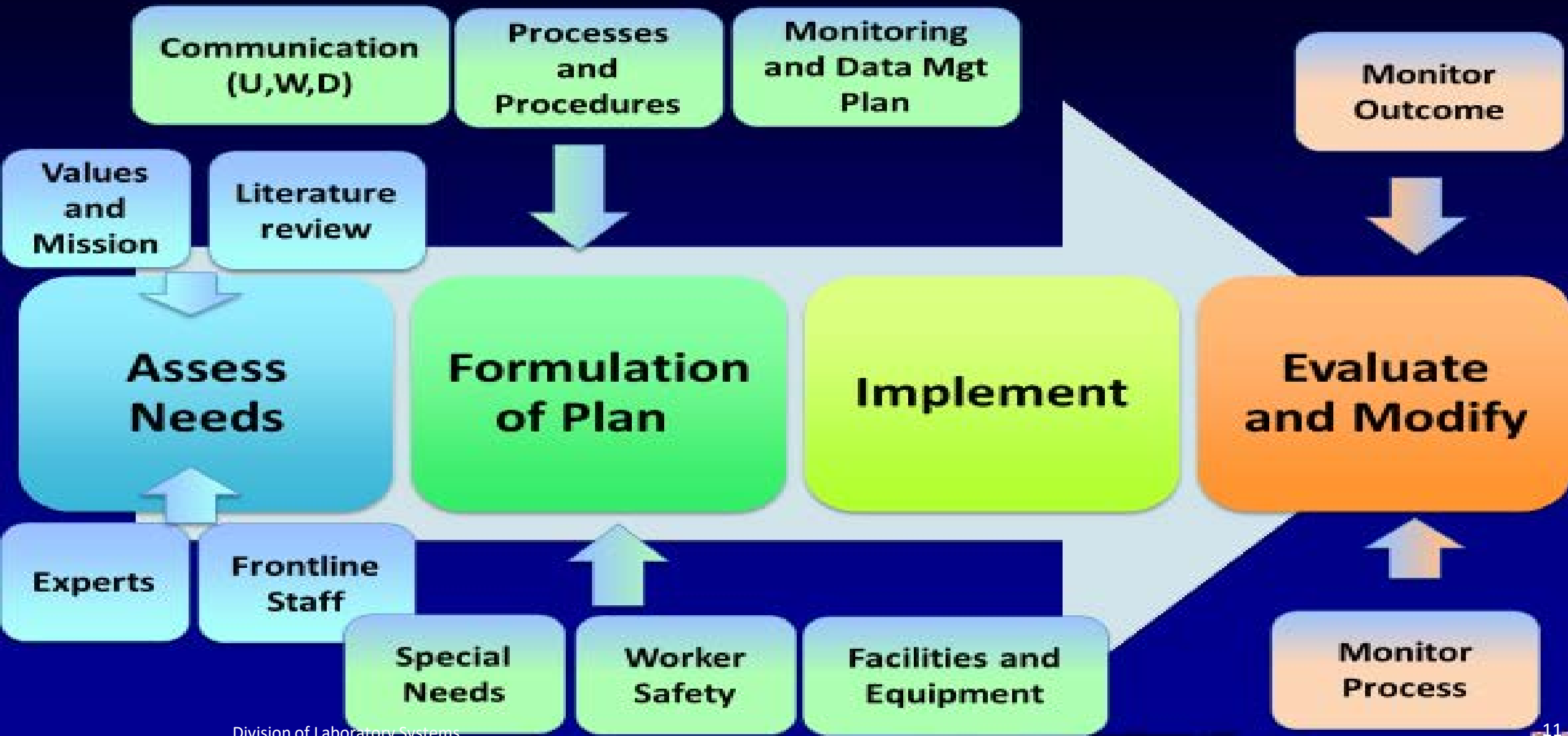
Emergency Management Cycle



Mortuary and Autopsy Services

- Three hospital system ~2000 beds
- Oversee three mortuaries. Capacities of 12/12/27.
- Autopsy facilities at only Flagship hospital (YNHH)
- TaskForce to Manage the mass fatality from COVID while protecting healthcare workers, and support research and education; headed by Director of Autopsy and Mortuary services

Surgical Pathology and Cytology Services Preparedness and Response Plan



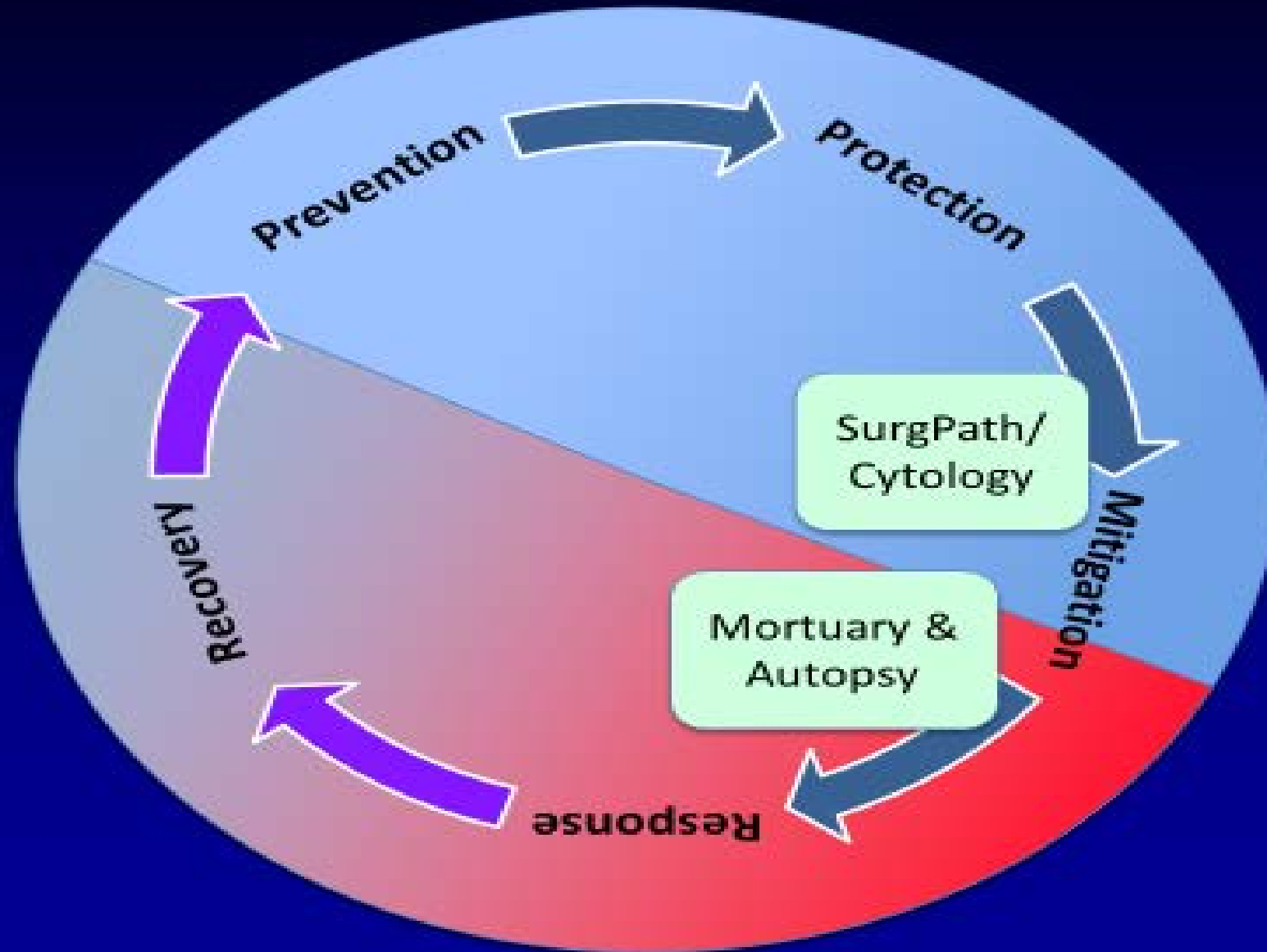
Mortuary and Autopsy Services Preparedness and Response Plan

- Facilities and Equipment
 - Portable Mortuary Units, Flexmorts, Security
- Communication
 - Experts (Office of the CME, CDC, DPH)
 - State and local services/ officials
 - Institutional experts and officials
 - CT Funeral Directors Association*
 - Floor Safety Managers*

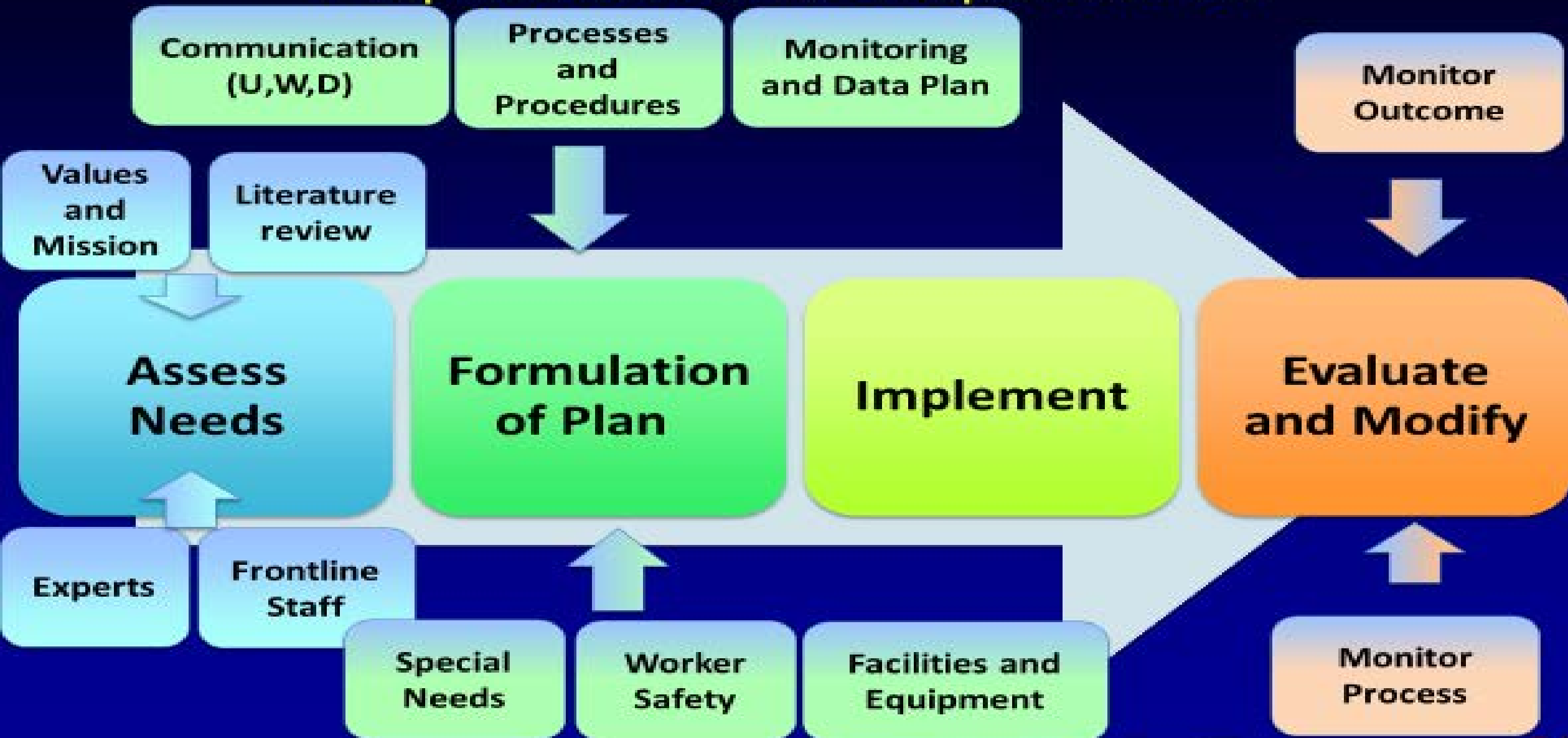
- Processes and Procedures
 - Direct to morgue discharge of decedents
 - Body bag misted with alcohol/wipe down.
 - New Label with identifiers glued to bag
 - Labeled COVID (later yellow body bags)
 - Education and Drills
- Worker Infection Control and Wellbeing
 - Elimination: Unnecessary personnel
 - Administrative controls (Seating and schedules)
 - Education and Training PPE

- Autopsies (Suspended due to PPE needs.. But..)
 - Recent report of death of Forensic Pathologist in Taiwan.
 - Nasal swab for PUI patients
 - Developing a protocol for a modified autopsy for COVID
 - Specific Reasoning for autopsy
 - Trained personnel; Must repeat PPE training
 - Process: Mist body with alcohol; no oscillating saw; no running of bowel
 - Procedure: In-situ examination (pulmonary embolus); Sections from all lobes of lung, liver, heart, trachea; other organs ?

Emergency Management Cycle



Surgical Pathology and Cytology Services Preparedness and Response Plan



Surgical Pathology & Cytopathology

Preparedness and Response

- Risk: Opportunity of exposure and Dose (Volume/time/concentration/infectivity)
- Only about 18% of LAI's where incident exposure is identified (SARSx3)
- Conduct a Job Hazard/Safety Analysis (? BEL's)
 - AEROSOL GENERATING!
- Eliminate exposure: All patients undergo a COVID test. But up to 30% (?) tests are false negatives; ? Most specimens should come in formalin

Challenges (Compared to OR's)

	Number of OR/Surgical Suites	All the Surgical Pathology
Issues	>65	2 (3)
Room Containment	Yes	No
Aerosol Generating Activities	Contained in rooms	Open (Bone saw room with ? Curtain); GI specimens cleaned with running water; Scalpels and forceps "swished" in water; FS "faced" in ? Containment settings
Attire	Clean scrubs– no entry otherwise	Street Clothes OK.
Traffic	Limited	We are all connected

Balancing Risk : When is it overkill?

Surgical Pathology and Cytology

- **High Risk Situations**
 - Frozen Section (High aerosolization risk)
 - ROSE (Rapid OnSite Evaluation for Cytology)
- Till we know more:
 - Eliminate (Why and will this give you an answer)
 - Substitute (rapid processing?; formalin fixation)
 - Reduce (blocks, sections at frozen section)
 - Modify work practices (Cleaning); Engineering controls
 - PPE (SCRUBS; N95 for sectioning technicians)
 - Administrative controls

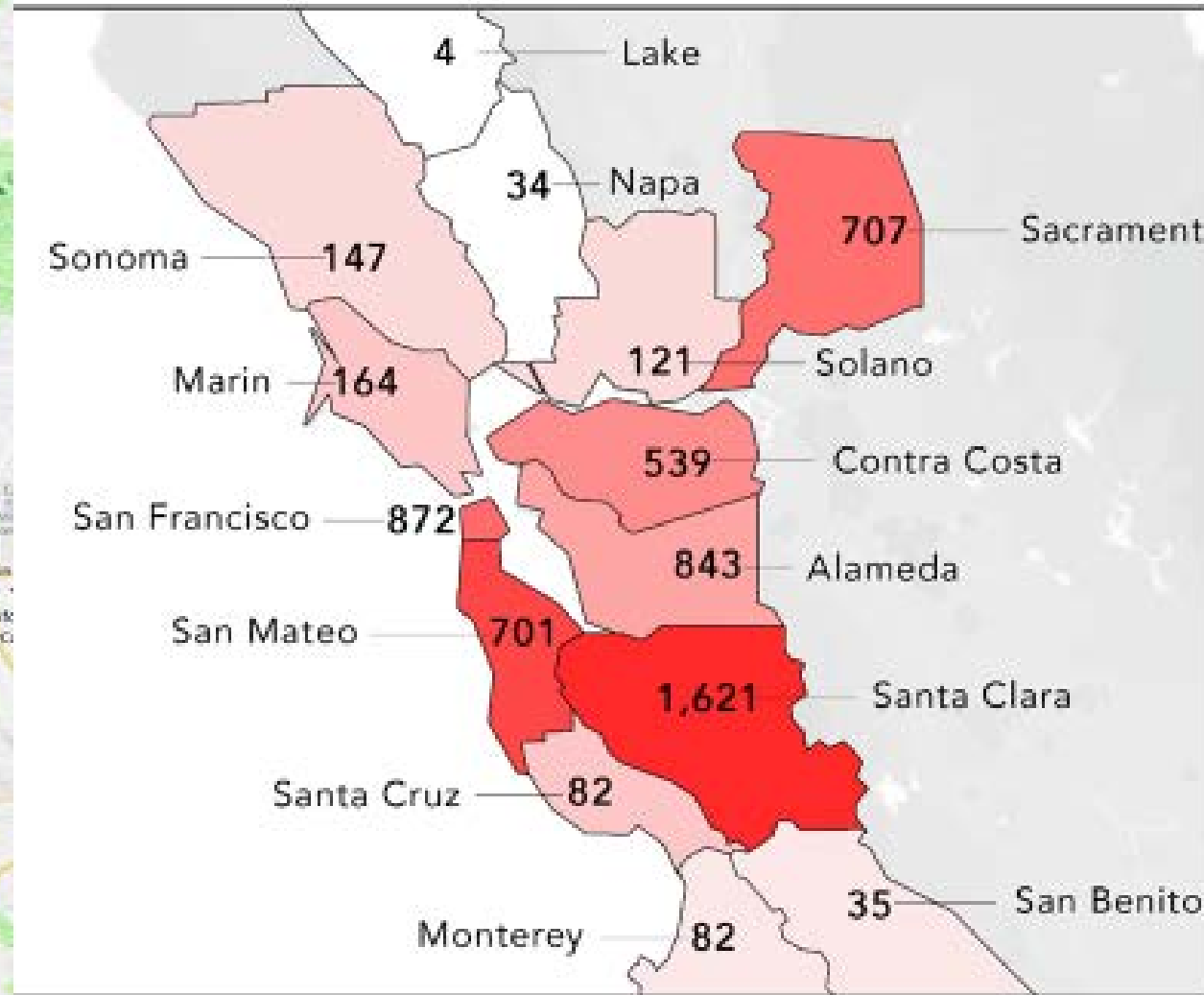
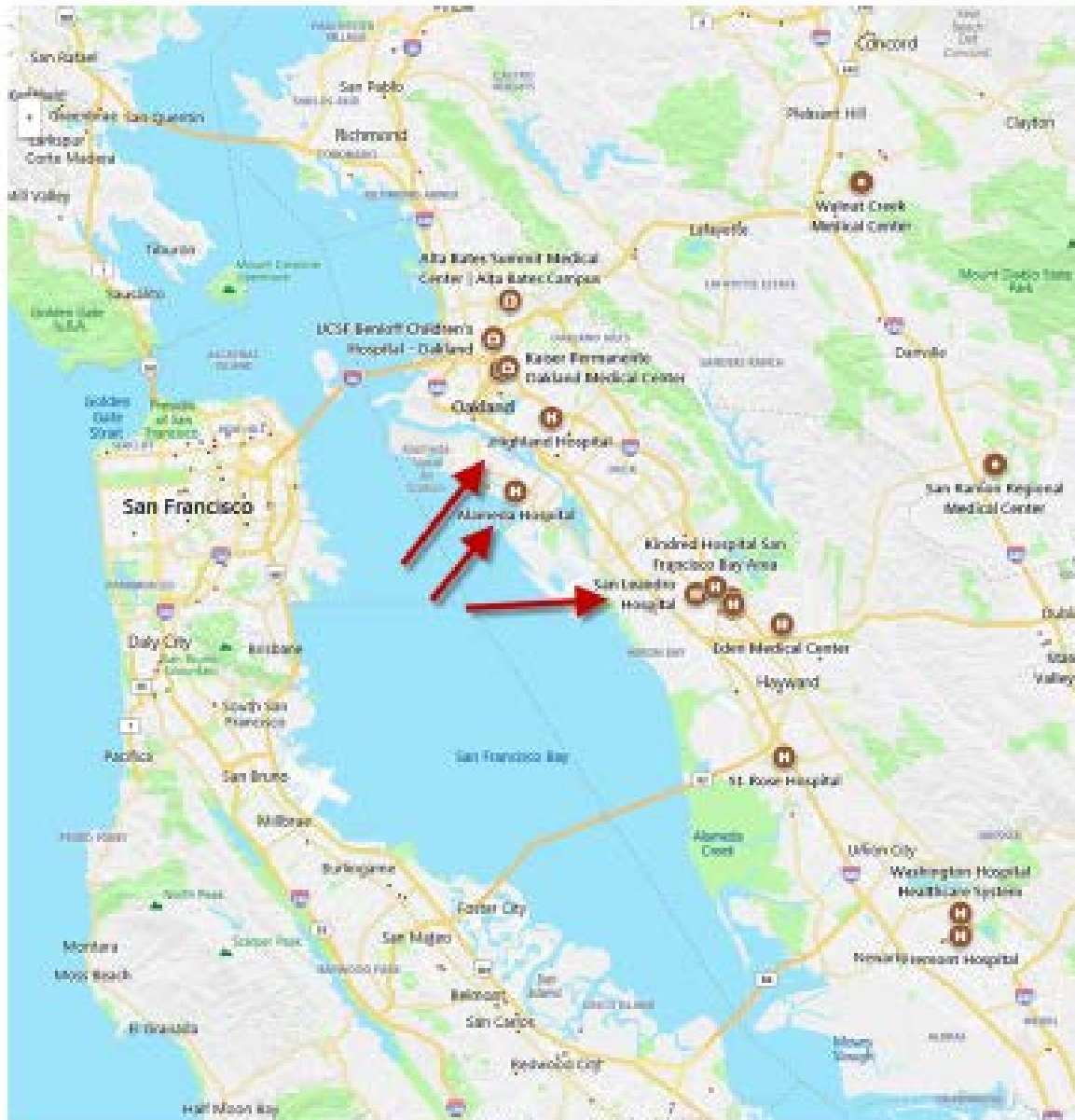
PPE use in Surgical Pathology

Donning	Doffing	Disposal
Scrubs- Resident and Faculty. Leave in Hospital	Where? Tamp down trash can before removing.	Area for removal and disposal of PPE ??
Shoe covers/ Bonnet/ Gown (arm covers ?)	First set of gloves/ no touch removal	Open Disposal of soiled and bloody PPE pose risk ??
Hand Hygiene	Remove shoe covers	
Face Mask (No touch technique)	Remove gown and second set of gloves (No touch technique)	Surface cleaning protocols to be changed?
Eyecover/ shield	Hand Hygiene	
	Face and Eyecover	
	Hand Hygiene	

COVID-19 at Alameda Health System

Valerie Ng, PhD MD
Chair, Laboratory Medicine & Pathology
Laboratory Director, Alameda Health System Clinical Laboratories
Alameda County, California





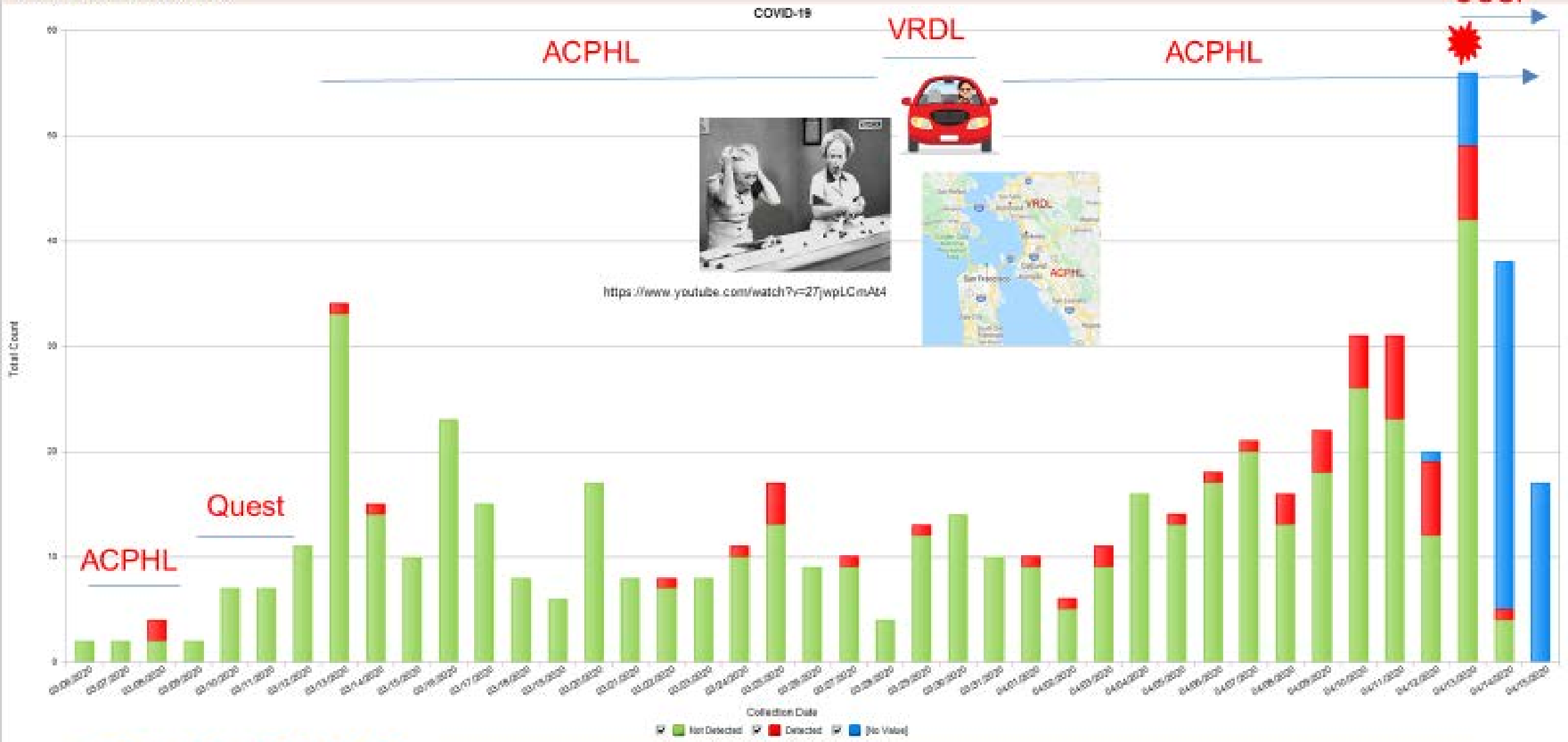
04/13/2020; <https://www.sfgate.com/bayarea/article/COVID-19-in-California-cases-deaths-how-many-15144233.php>

COVID-19 Lab Results

COVID-19



COVID-19 Lab Results

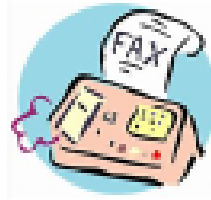


Barriers

- Alameda County Public Health Laboratory (ACPHL)
 - CA regulations: Public Health Microbiologists (PHMs) only
 - Relaxed by Governor Newsom 03/30/2020 Executive Order N-39-20 (<https://www.gov.ca.gov/wp-content/uploads/2020/03/3.30.20-EO-N-39-20-text.pdf>)
 - 5) To facilitate the continued provision of care to individuals affected by the COVID-19 outbreak, the Director of the Department of Consumer Affairs may to the extent necessary and only for the duration of the declared emergency, **waive any of the professional licensing requirements and amend scopes of practice in Division 2** of the Business and Professions Code, and any accompanying regulations. Professional licensing requirements should be interpreted broadly to effectuate the purposes of this executive order, and they include, but are not limited to, the

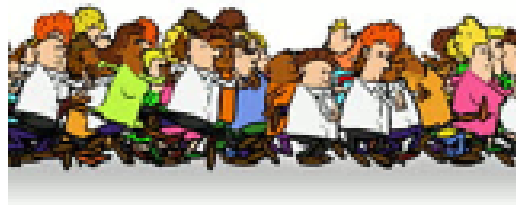
Opportunities

- “Just in time” inventory incompatible with pandemics
 - swabs, VTM/UTM
- Connectivity
- ACPHL testing
 - Saturday & Sunday
 - Couriers



Opportunities

- In house rapid testing for admitted patients
 - Critically needed to manage PPE, isolation, staffing, ventilators, etc.
 - Technology feasible for a non-molecular laboratory sans BSL3 facility
 - Not immediately available commercially
 - National allocation strategy for distribution



In Vitro Diagnostic Product	Date of EUA Issuance	Letter of Authorization
Xpert Xpress SARS-CoV-2 test (Cepheid)	March 20, 2020	Letter of Authorization (PDF, 140 KB)
ID NOW COVID-19 (Abbott Diagnostics Scarborough, Inc.)	March 27, 2020	Letter of Authorization (PDF, 356 KB)

Distractions

- Serological testing
 - Aggressive marketing to Emergency Departments

**NOT
INTERESTED**

A: As stated in Section IV.D of the FDA's *Policy for Diagnostic Tests for Coronavirus Disease-2019*, the FDA does not intend to object to the development and distribution by commercial manufacturers, or development and use by laboratories, of serology tests to identify antibodies to SARS-CoV-2, where the test has been validated, notification is provided to FDA, and information along the lines of the following is included in the test reports:

- This test has not been reviewed by the FDA.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2>

Beacons of Truth and National Assistance



- ASM
 - ClinMicroNet
 - Public Affairs (Peggy McNult, Melissa Miller)
- FDA – lightning fast EUAs
 - Instructions for Use postings
- CDC –
 - real time guidances & updates
 - COVID19 response weekly call
 - CDC Laboratory Outreach Communication System (LOCS@cdc.gov)
- CMS – Regulatory updates
 - 'near patient' = 'waived' (EUA only)

Local Heroes – State & Alameda County



- Public Health Department
- Public Health Laboratories
 - Provided testing when there was no alternative
 - Seamless vertical integration between ACPHL and VRDL/CDPH
 - Rapid cycle change



Alameda County Public Health Department

Division of Communicable Disease Control & Prevention
Public Health Laboratory



COVID-19 Coding and Reimbursement

Sarah Shirey-Losso, Centers for Medicare and Medicaid Services
(CMS)



Updates on Review Process, Quality, Validation, and Serology Testing

Tim Stenzel, MD, PhD
Sara Brenner, MD, MPH
U.S. Food and Drug Administration (FDA)



Food and Drug Administration (FDA)

COVID-19 Emergency Use Authorization (EUA)

Information: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

COVID-19 Frequently Asked Questions: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/coronavirus-disease-2019-covid-19-frequently-asked-questions>

COVID-19 Updates: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov>

Food and Drug Administration (FDA)

COVID-19 Diagnostic Development: CDRH-EUA-Templates@fda.hhs.gov

Spot Shortages of Testing Supplies: 24 hour support available

1. Call 1-888-INFO-FDA (1-888-463-6332)
2. Then press star (*)

CDC Social Media



Facebook: <https://www.facebook.com/CDC>



Twitter: <https://twitter.com/cdcgov>



LinkedIn: <https://www.linkedin.com/company/cdc>

Thank You For Your Time!

Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center.

